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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/050,425	01/15/2002	Gregory R. Mundy	432722002601	7663

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EXAMINER

GITOMER, RALPH J

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/050,425

Applicant(s)
Mundy et al.

Examiner
Ralph Gitomer

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, and 7-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, and 7-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

The amendment received 1/15/2002 has been entered and claims 1, 2, 7-14 are currently pending in this application. Priority is granted to 7/10/1998. Please inform the examiner as to how 09/361,775 which is a CIP, differs from its parent application 09/113,947 to confirm the proper priority date. And please inform the examiner of any related cases, pending, allowed or abandoned.

This application contains sequence disclosures at page 13, lines 20 and 21, that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for one or more of the reasons set forth on the attached form Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequences and/or Amino Acid Disclosures Sequence. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) for the response to this action to be complete.

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

- 5 The oath or declaration is defective because:
It was not executed in accordance with either 37 CFR 1.66 or 1.68. G. Rossini has not provided a full name.

10 The submission of about 95 references received at various times in various files is noted, however it would appear the references are directed toward non-analogous art. None appear to be directed to hair growth treated by any of the classes of claimed compounds. The Applicants are invited to particularly point out any references which may be either specifically
15 analogous or definitely pertinent to the claimed invention. Note 24 USPQ2d Golden Valley Microwave Foods Inc. v. Weaver Popcorn Co. Inc. where the patent applicant has duty not just to disclose prior art reference but to make disclosure in such way as not to "bury" it within other disclosures of less relevant prior art.

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The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,410,512. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound, PSI of '512 is a peptidyl aldehyde.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

5 (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15 Claims 1, 2, 7-13 are rejected under 35 U.S.C. 102(a) as being anticipated by Bathurst.

Bathurst (6,495,532) with a priority date of March 19, 1997, entitled ~~Compositions~~ Compositions Containing Lysophosphotidic Acids Which Inhibit Apoptosis and Uses Thereof ~~teaches~~ teaches in column 3 lines 5-
20 6, growth factors and calpain inhibitors which prevent apoptosis. In column 12 line 23, hair loss is treated. In column 40 last full paragraph, hair loss can be caused by apoptosis of the cells of the hair follicles. Therefore, the compositions are suitable for use in topical treatment of skin to prevent continued hair
25 loss.

Claims 1, 7-11 are rejected under 35 U.S.C. 102(b) as being anticipated by each of Miller and Horvitz.

Miller (WO 96/33268) published October 1996, entitled ~~Apopain~~ teaches on page 1, peptidyl derivatives which are modulators of activity of pro-apoptotic cysteine proteinases. They may be used to treat alopecia. On page 16 bridging to page 24, peptidyl aldehydes are shown.

Horvitz (WO 93/25694) published December 1993, entitled ~~Inhibitors of CED-3 and Related Proteins~~ teaches on page 3, peptide aldehydes may be useful for inhibiting cell deaths. On page 3, conditions characterized by cell death such as hair loss can be treated. On page 9, drugs which reduce cell deaths are useful for treatment of hair loss. On page 18, by controlling cell death, one could cause or prevent hair loss. On page 30 various peptide aldehydes are taught as inhibitors of protease activity.

All the features of the claims are taught by the above references for the same function as claimed.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to provide written description for the presently claimed ~~peptidyl aldehyde~~.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph,
as containing subject matter which was not described in the
specification in such a way as to enable one skilled in the art
to which it pertains, or with which it is most nearly connected,
5 to make and/or use the invention.

On page 15 line 9 of the specification, EST is shown on page
15 of the specification, but is not described in any meaningful
way to identify it.

10 Claims 2 and 12-14 are rejected under 35 U.S.C. § 112,
second paragraph, as being indefinite for failing to particularly
point out and distinctly claim the subject matter which applicant
regards as the invention. Each of the following applies in all
occurrences.

15 In claims 2 and 12 ~~the~~ said compound ~~is~~ lacks antecedent basis.
In claim 14 EST is not understood as to what compound may be
intended.

20 The title of the invention is not aptly descriptive. A new
title is required that is clearly indicative of the invention to
which the claims are directed.

The Abstract of the Disclosure is objected to because it is
not directed to the claimed invention. Correction is required.

25 See M.P.E.P. § 608.01(b).

The disclosure is objected to because of the following informalities: The headings and format of the specification are not standard. Appropriate correction is required.

5 The following prior art pertinent to applicant's disclosure is made of record and not relied upon:

Mundy (2002/0111292 and 2002/0107203) may be related cases.

Horvitz (5,962,301) teaches various peptide aldehydes.

Horvitz (WO 96/25946) teaches various peptide aldehydes.

10 Mundy (6,492,333) filed April 9, 1999, with a different inventive entity, claims treating bone with PSI.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph
15 Gitomer whose telephone number is (703) 308-0732. The examiner can normally be reached on Tuesday-Friday from 8:00 am - 5:00 pm. The examiner can also be reached on alternate Mondays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703)
20 308-4743. The fax phone number for this Art Unit is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235. For 24 hour access to patent application information 7 days per week, or for filing
25 applications electronically, please visit our website at

Serial No. 10/050,425
Art Unit 1651

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Center for more information.

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Ralph Gitomer
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